REMARKS

Claims 21-23 are pending in this continuation application. No claims have been cancelled. No claims have been added. Claim 21 has been amended.

Claims 21-23 have been rejected under 35 U.S.C § 112, first paragraph, as being non-enabled by the specification. It is the Examiner's view that the specification is enbabling only for reducing the risk of cervical dysplasia or cervical carcinoma not for treating or preventing these disorders. While applicants do not agree with the Examiner's view regarding this issue, in an effort to move prosecution along in this case the claims have been amended, as set forth above, to address the rejection issued under § 112. In view of these claim amendments, applicants believe that the rejection has been traversed.

Claims 21-23 have been rejected under 35 U.S.C § 103(a) over Wood et al. in view of Jackson '011). Applicants request that this rejection be withdrawn since these references do not teach or even suggest the claimed method. Wood merely restates what is already known in the art, i.e., the use of oral contraceptives can interfere with folic acid absorption and/or metabolism of folic acid. (See also, the instant specification at page 3, lines 18-25). Jackson '011 reiterates what is known in the art, as also set forth in the instant specification and discussed above, that women with decreased levels of folic acid are subject to increased risks for conditions such as cervical dysplasia and cervical cancer.

The combination of references relied on by the Examiner neither teaches nor suggests a method for administering folic acid wherein folic acid is administered in combination with an oral contraceptive as a single pharmaceutical composition. Such a method insures that as a woman regularly takes her oral contraceptive she automatically is administered the required amount of folic acid, thus eliminating the risk of cervical dysplasia and cervical carcinoma associated with insufficient folic acid levels.

Nowhere is this taught or suggested by the combination of Wood and Jackson. In fact, if these references were combined as suggested by the Examiner all they would teach is the administration of a dietary supplement combining vitamins, minerals and folic acid to address the risk factors associated with low folic acid levels. Only through applicants' own teachings could one skilled in the art be led to the claimed method, wherein folic acid is administered in combination with an oral contraceptive to insure that women using oral

contraceptives maintain regular and sufficient folic acid supplementation. Such hindsight reconstruction of the prior art using applicants' own teachings is clearly impermissible.

The Examiner cites In re Fine, 5 USPQ 2d 1596 (Fed. Cir. 1988) and In re Jones, 21 USPQ 2d 1941 (Fed. Cir. 1992) in support of the proposition that the rational for combining or modifying the prior art need not be expressly stated in the art. According to the Examiner's reading of these cases, it is sufficient for the rational to be either expressly or impliedly contained in the prior or that the rational may be reasoned from knowledge generally available to those skilled in the art, established by general principles, or legal precedent.

A fair reading of these cases does not permit such broad leeway in establishing the rational for combining references. The rational for combining or modifying the art is limited to an objective teaching in the art or to an adequate suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In both Fine and Jones the Court found that the PTO had failed to provide proper motivation for combining the references at issue because there was no such objective teaching or adequate suggestion, and this is precisely the situation in the present case. As discussed above, even if Wood and Jackson were combined as argued for by the Examiner they would not lead to the claimed invention. Only through impermissible hindsight based on applicants' own teachings is the claimed invention rendered obvious in view of these references.

Accordingly, applicants request that the rejection issued under § 103(a) be withdrawn.

Enclosed herewith is a Supplemental Information Disclosure Statement. The Statement includes references relating to contraceptive pill paks in which the 7 placebo tablets typically included in such paks are formulated with folic acid. Such a pill pak is also disclosed in the present case. US Patent No. 5,254,572 suggest the combination of vitamin B6 and an oral contraceptive in the same dosage form. However, there is no teaching or suggestion in this reference, or any of the other references submitted herewith, of the claimed method of administering folic acid.

In view of the foregoing, applicants believe that claims 21-23 are in condition for allowance and a Notice of Allowance directed to these claims is requested at the earliest possible date.

Applicants hereby petition for a two-month extension of time in order to respond to the outstanding Office Action. Please charge the fee of $410.00 required under 27 C.F.R. § 1.17 (a)(2), and any additional fees that may be required to Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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